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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,198	12/02/2003	Constance M. John	3157.00011	3458

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EXAMINER	
REDDIG, PETER J	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/726,198	JOHN ET AL.	
	Examiner	Art Unit	
	Peter J. Reddig	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) 11-17 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-7,8-10,18-24 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to a composition comprising an effective amount of N-terminally truncated galectin-3 polypeptide and a pharmaceutically acceptable carrier, classified in class 530, subclass 350.

(Upon election of Group I, applicant must further choose SEQ ID NO: 1 or SEQ ID NO: 2: as each polypeptide represents an independent invention, not a species.)

II. Claims 8-10, drawn to a method of treating a tumor in a patient by administering to a patient in need of treatment an effective amount of N-terminally truncated galectin-3, classified in class 514, subclass 2.

(Upon election of Group II, applicant must further choose SEQ ID NO: 1 or SEQ ID NO: 2: as each polypeptide represents an independent invention, not a species.)

III. Claims 18-20, drawn to a nucleic acid sequence encoding an N-terminally truncated galectin-3, classified in class 536, subclass 23.1.

(Upon election of Group III, applicant must further SEQ ID NO: 1 or SEQ ID NO: 2: as each polypeptide represents an independent invention, not a species.)

IV. Claims 21 and 22, drawn to a method of treating a tumor in a patient by administering to a patient in need of treatment an effective amount of a nucleic

acid sequence encoding an N-terminally truncated galectin-3, classified in class 514, subclass 44.

(Upon election of Group IV, applicant must further choose SEQ ID NO: 1 or SEQ ID NO: 2: as each polypeptide represents an independent invention, not a species.)

V. Claims 23 and 24, drawn to antibody that specifically binds to carbohydrate ligands of galectin-3, classified in class 530, subclass 130.1.

(Upon election of Group V, applicant must further choose SEQ ID NO: 1 or SEQ ID NO: 2: as each polypeptide represents an independent invention, not a species.)

Claims 11-17 are withdrawn because it is not possible to determine for which Group they are intended, upon amendment it will be rejoined to the appropriate Group for examination.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the protein of Group I could be used as molecular weight marker in immunoblotting or as antigen for antibody generation.

Furthermore, searching all of the claims (i.e., both Groups) would invoke a burdensome search because the inventions have been classified separately. Thus, each invention has attained

recognition in the art as a separate subject for inventive effort, and also a separate field of search. This would necessitate different searches in the patent and or non-patent literature and the consideration of different patentability issues.

3. The protein of Groups I is related to the nucleic acid of Group III by virtue of the fact that the nucleic acid codes for the protein. The nucleic acid molecule has utility for the recombinant production of the protein in a host cell. Although the nucleic acid and the protein are related, since the nucleic acid encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, nucleic acid can be used for processes other than the production of protein, such as nucleic acid hybridization assays.

Furthermore, searching the inventions of Groups I and III together would impose a serious search burden. In the instant case, the search of the polypeptides and polynucleotides are not coextensive. The inventions of Groups I and III have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate database. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequences of interest there may be journal articles devoted solely to polypeptides, which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers, which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore, is not coextensive. As such, it would be burdensome to search the inventions of Groups I and III.

4. Inventions of Groups I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of

operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to a product and an unrelated method. Group I is broadly drawn to a composition comprising a N-terminally truncated galectin-3 protein. Group IV is drawn to a method of treating a tumor using a nucleic acid sequence encoding N-terminally truncated galectin-3. The method of Group IV does not require the protein product of Group I and the protein product of Group I can not be used in the method of Group IV since the claimed methods only encompasses using polynucleotides.

5. Furthermore, searching all of the claims (i.e., both Groups) would invoke a burdensome search because the inventions have been classified separately. Thus, each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. This would necessitate different searches in the patent and or non-patent literature and the consideration of different patentability issues

6. The polypeptide of Group I and the antibody of Group V are patentably distinct for the following reasons:

While the inventions of both Group I and Group V are polypeptides, in this instance the polypeptides of Group I represent N-terminally truncated galectin-3, whereas the polypeptides of Group VI encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarily determining regions (CDR) that function to bind an epitope. Thus the polypeptides of Group I and the antibodies of Group V are structurally distinct molecules; any relationship between a polypeptide of Group I and an antibody of Group V is

dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

7. In this case, the polypeptides of Group I encompass large molecules, which contain potentially hundreds of regions to which an antibody may bind, whereas the antibody of Group VI is defined in terms of its binding specificity to carbohydrate ligands of galectin-3. Furthermore, searching the inventions of Group I and Group V would impose a serious search burden. The inventions have separate status in the art as shown by their different classifications. A polypeptide and an antibody that binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of Group V. Furthermore, antibodies that bind to an epitope of a polypeptide of Group I may be known even if a polypeptides of Group I is novel. In addition, the technical literature search for the polypeptides of Group I and the antibody of Group V are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

8. Inventions of Groups II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to a method and an unrelated product. Group II is broadly drawn to a method of treating a tumor using a N-terminally truncated galectin-3 protein. Group III is drawn to a nucleic acid sequence encoding an N-terminally truncated galectin-3. The method of Group II does not require the nucleic acid product of Group III and the nucleic acid product of Group III

can not be used in the method of Group II since the claimed method only encompasses using polypeptides.

Furthermore, searching all of the claims (i.e., both Groups) would invoke a burdensome search because the inventions have been classified separately. Thus, each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. This would necessitate different searches in the patent and or non-patent literature and the consideration of different patentability issues.

9. Inventions II and IV are directed to related methods of treating a tumor. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods utilize distinct steps not required in the other method. Group II has the distinct step of administering a N-terminally truncated galectin-3 protein to a patient and Group IV has the distinct step of administering a nucleic acid encoding a N-terminally truncated galectin-3 to a patient.

Furthermore, searching all of the claims (i.e., both Groups) would invoke a burdensome search because the inventions have been classified separately. Thus, each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. This would necessitate different searches in the patent and or non-patent literature and the consideration of different patentability issues

10. Inventions of Groups II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of

operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to a method and an unrelated product. Group II is broadly drawn to a method of treating a tumor using a N-terminally truncated galectin-3 protein. Group V is drawn to antibody that specifically binds to carbohydrate ligands of galectin-3. The method of Group II does not require the antibody product of Group V and the antibody product of Group V cannot be used in the method of Group II since the claimed method only encompasses using N-terminally truncated galectin-3 polypeptides.

Furthermore, searching all of the claims (i.e., both Groups) would invoke a burdensome search because the inventions have been classified separately. Thus, each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. This would necessitate different searches in the patent and or non-patent literature and the consideration of different patentability issues.

11. Inventions of Groups III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the nucleic acids of Group III could be used as probes in nucleic acid hybridization assay like Southern or Northern analysis.

Furthermore, searching all of the claims (i.e., both Groups) would invoke a burdensome search because the inventions have been classified separately. Thus, each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search.

This would necessitate different searches in the patent and or non-patent literature and the consideration of different patentability issues.

12. Inventions of Group III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). .

The polynucleotides of Groups III are unrelated to the antibodies of Groups V because they are structurally distinct molecules and the nucleic acid of Group III does not encode the antibodies of Group V.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

13. Inventions of Groups IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to a method and an unrelated product. Group IV is drawn to a method of treating a tumor using a nucleic acid encoding a N-terminally truncated galectin-3 protein. Group V is drawn to antibody that specifically binds to carbohydrate ligands of galectin-3. The method of Group II does not require the antibody product of Group V and the antibody product of Group V can not be used in the method of Group IV since the claimed method only encompasses using nucleic acids encoding N-terminally truncated galectin-3 polypeptides.

Furthermore, searching all of the claims (i.e., both Groups) would invoke a burdensome search because the inventions have been classified separately. Thus, each invention has attained

recognition in the art as a separate subject for inventive effort, and also a separate field of search. This would necessitate different searches in the patent and or non-patent literature and the consideration of different patentability issues.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

14. Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

16. Applicant is advised that the reply to this restriction requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Peter J. Reddig, Ph.D.
Examiner
Art Unit 1642

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

PJR